PART 2 OPERATIONS

3000 Biomedical Research Activities

Records which document operations and activities which are part of the NIH intramural program, contract-supported extramural program, and/or any collaborative research and development agreements (CRADAs) in support of biomedical research activities.

EXCLUDED from this section are

- (1) Files which document administrative management to service activities covered by Part 1.
- (2) Files created or used to provide information on program activities to the public (see section 8000).

A. <u>Medical Arts and Photography</u>

Photographs, motion pictures and video tapes related to patients' physical conditions, manifestations and treatment.

EXCLUDED from this section are

- (1) Other audio-visual materials (see item 8100);
- (2) Photographs and motion pictures delivered to users (Dispose of according to disposition instructions for related files).
- 3000-A-1 <u>Slides and other visual materials</u> used in exhibits, publications, and other media.

Located in ORS, Medical Arts and Photography Branch.

<u>Disposition</u>: Destroy when superseded or when no longer needed for branch purposes.

2000-A-2 <u>Photographic Materials</u>: Consisting of still and motion pictures relating to patients' physical conditions, manifestations, and treatment. Biomedical data revealed by these pictures are summarized in permanently retained patients' clinical charts. Some, however, may be involved in later research, either in general biomedical areas or in relation to the specific patient.

<u>Located in ORS</u>, Medical Arts and Photography Branch.

<u>Disposition</u>: DISPOSAL NOT AUTHORIZED.

3000-A-3 Video tapes of medical research procedures in the Clinical Center.

Disposition: Erase tapes for reuse when 3 years old.

3000-A-4 <u>Medical taping record sheets</u>, listing patient video tape made, dates made, and related data.

Disposition: Destroy when 5 years old.

B. <u>Environmental Services</u> (see section 1300-B).

C. <u>Veterinary Services</u>

Records of the Veterinary Resources Branch of the Office of Research Services.

EXCLUDED from this section are Administrative records of the branch (see item 1100-M-1-b).

Animal research project data files, concerning various aspects of animal pathology, accumulated by each researcher and containing a variety of statistical and analytical data. Results of research are published in professional journals.

<u>Disposition</u>: Destroy when data are obsolete or when no longer needed in research.

3000-C-2 Requests for animals, related to specified animals needed for investigators in NIH. Forms are coded for computer input.

Disposition: Destroy when request data are put into computer.

Animal production records, recording various weaning data and other statistics on a weekly basis. Summarized in branch level reports.

<u>Disposition</u>: Destroy when 3 years old.

Animal disease investigation reports, prepared at the request of investigators, showing examination, pathology, and treatment data for each animal involved.

<u>Disposition</u>: Destroy when 6 years old.

3000-C-5 <u>Animal health certificates</u>, concerning the health of animals received by the branch

<u>Disposition</u>: Destroy when 5 years old.

3000-C-6 Control records relating to procedures for introducing rodents into NIH from sources where disease-free environment is open to question. Contains applications for permits, quarantine reports, and related papers.

<u>Disposition</u>: Destroy 6 years after expiration of permit.

3000-C-7 Pedigree history and related records, providing data concerning the generational history of each strain, related weaning information, and other key genetic data. Contain pedigree registration forms, registration history records, pedigree documentation which may be provided by animal suppliers, necropsy records, certain weight records, breeding performance history records, and quarantine records.

Disposition: DISPOSAL NOT AUTHORIZED at this time.

3000-C-8 <u>Hospital surgery, treatment and autopsy records</u>

<u>Disposition</u>: Destroy when investigator involved leaves NIH, or when 5 years

old, whichever is later.

3000-C-9 <u>Surgery room logs</u>

Disposition: Destroy when 3 years old.

3000-C-10 <u>Experiment Protocol Files</u>: Agreements by investigators and experimenters that certain standards and procedures will be observed.

Disposition: Destroy when protocol is no longer in force.

3000-C-11 <u>Animal inventory adjustment records</u>, recording blood issues and various animal issue transactions.

<u>Disposition</u>: Destroy when 1 year old.

3000-C-12 <u>Records of Disposition of Laboratory Animals</u>: Various procurement data required by the Department of Agriculture.

Disposition: Destroy when 5 years old.

3000-C-13 Records relating to the care and maintenance of animals not discussed above: Including records of food, bedding, caging, and the like.

<u>Disposition</u>: Destroy when 3 years old.

D. Biomedical Engineering and Instrumentation

Records of the Biomedical Engineering and Instrumentation Branch of ORS.

EXCLUDED from this section are
Branch administrative files (see item 1100-M-1-b).

3000-D-1 <u>Service requests</u> for instrumentation and equipment maintenance.

<u>Disposition</u>: Destroy 3 years after completion of service.

3000-D-2 <u>Commercial catalogs and similar reference materials.</u>

Disposition: Destroy when superseded or obsolete.

- Project Folders accumulated and maintained by the individual technician during the life of each project. They contain engineering project sheets, documenting the inception of the project and describing the problem; notes and data of various kinds, reports of visits, sketches, calculations, manufacturers' literature, specification sheets, photographs, and a variety of other unstandardized materials and a "close-out form," which formally closes the project as well as the project file. The "close-out form" includes a recommendation as to whether or not the folder should be destroyed.
 - a. Files which, in the opinion of the Section Chief, may be involved in later patent problems, or which relate to systems still in use or likely to be in use for the indefinite future, or which may have special applications in the

future.

<u>Disposition</u>: DISPOSAL NOT AUTHORIZED. Review closed files every 5 years for possible destruction.

b. All other project files.

<u>Disposition</u>: Destroy 2 years after close of project.

- 3000-D-4 <u>Engineering Drawings Developed in Connection with Projects</u>: These original drawings document instrumentation and other systems developed by the branch.
 - a. Drawings, which in the opinion of the Section Chief, have continuing value for technical, research, or legal purposes.

<u>Disposition</u>: DISPOSAL NOT AUTHORIZED. Review closed files every 5 years for possible destruction.

b. All other drawings.

<u>Disposition</u>: Destroy 5 years after completion of project.

3000-D-5 <u>Engineering Notebooks</u>: These are essentially non-record in nature, containing detailed notes, computations and other day-to-day data compiled by the technician for each project.

<u>Disposition</u>: Destroy when data are of no further technical and research value.

E. Clinical Care

- i. General (reserved)
- 3000-E-10 Occurrence Reports, prepared as part of the Clinical Center quality assurance and safety programs, covering quality assurance records, FDA device reports, and FDA drug interaction reports. (formerly Incident and accident reports 1300-B-6)

Location: All IC's

<u>Disposition</u>: Destroy the recordkeeping copy when 2 years old.

<u>Electronic version</u>: Delete after recordkeeping copy has been produced or when no longer needed for reference or updating.

ii. Patients, Clinical Research Volunteers and Donors

Records about individual patients, clinical research volunteers and blood donors at the NIH Clinical Center.

WARNING: Records which can be retrieved by individual identifiers must be maintained and disposed of in a manner which will protect the individual's right to privacy.

EXCLUDED from this section are:

- (1) NIH employee health records (see item 2300-792-1 through 6);
- (2) Administrative records of the Clinical Center (see section 1100);
- (3) Records containing patient data used in operation of the Nutrition Department (see subsection 2600-C-i);
- (4) Records containing patient data used in operation of the Transfusion Medicine Department (see item 2600-C-ii);
- (5) Records containing patient data used in operation of the Pharmacy Department (see subsections 2600-C-iii and iv);

Records containing patient data used in operation of nursing, surgical and outpatient data incorporated into biomedical research files (see sections 3000-G through K).

3000-E-20 <u>Pre-admission files</u>, relating to referrals of potential patients by physicians and Members of Congress, containing incoming and outgoing correspondence.

Located in Office of Clinical Reports and Inquiries.

a. Files on Congressional Referrals.

<u>Disposition</u>: Destroy when 3 years old.

b. All other files.

<u>Disposition</u>: Destroy when 2 years old.

3000-E-21 <u>Diagnostic Cardiac Records</u>, Comprising EKG and Holter Tracings. (tracing by products). NOTE: Formal reports are maintained as a permanent part of the Clinical Center medical record.

<u>Disposition</u>: Transfer to the Federal Records Center when 10 years old. Destroy when 20 years old.

Medical Records Case Files of Patients of the NIH Clinical Center, filed by the unit system, using hospital number and patient name. Each medical record includes the complete record of admissions and medical treatment for a patient accepted in a research project. Inactive records for patients who have not received treatment for a period of five consecutive years will be microfilmed periodically.

(NOTE: These records are part of Privacy Act System of records 09-25-0099)

Disposition:

- a. <u>Recordkeeping Paper File</u> Destroy when microfilm has been accepted.
- b. <u>Microfilm File</u> Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference.
 These records must be microfilmed in accordance with FPMR 101-11.504.
- 3000-E-23 Requests for Medical Records

Disposition: Destroy when 1 month old.

3000-E-24 <u>Patient Report Files</u>: Reports of findings in laboratory analysis, placed on microfiche for reference and research.

<u>Located in CC</u>, Clinical Pathology Department.

<u>Disposition</u>: Destroy the recordkeeping copy 6 months after report is microfiched

3000-E-25 <u>Microfiche copies of patient reports</u>

Located in Clinical Pathology Department.

<u>Disposition</u>: Destroy when 7 years old.

3000-E-26 <u>Diagnostic radiological records</u>, comprising X-rays and other roentgenographic images produced by various devices and procedures such as body and head scans created by computerized trans-axial tomography. Files include positive photographic images resulting from ultrasound procedures and related studies and interpretations.

Located in Diagnostic Radiology Department.

a. Patients' radiological records.

Disposition: Retain in Diagnostic Radiology Department for 10 years from (1)

latest patient activity, or (2) reference request for the film or (3) request from appropriate clinical program for retention of the record. Transfer records to the Federal Records Center when file becomes inactive. Destroy 30 years after files become inactive.

b. Extra copies of radiological interpretations.

Disposition: Destroy when 1 year old.

3000-E-27 <u>Diagnostic Radiology Patient control cards</u>, maintained as an index of patients from 1953 to 1976, when an automated machine readable hospital information system was installed. Shows patient name, number, physician, admission and discharge dates. Data from these cards were placed retroactively into the system.

Located in Diagnostic Radiology Department.

Disposition: Destroy in 1981.

3000-E-28 <u>Positron Emission Tomography (PET) Files,</u> consisting of various electronic images of body and organ PET scans on patients. Files include interpretations.

<u>Located in</u>: CC, Positron Emission Tomography Department.

<u>Disposition</u>: Official electronic copy: Retain on-site for 50 years or expiration of the patient or subject, whichever is longer. Destroy when 50 years old.

3000-E-29 <u>Nuclear Medicine Patient card files</u>, summarizing essential data on each patient tested in the department. Used for quick reference.

Located in Nuclear Medicine Department.

<u>Disposition</u>: Destroy 4 years after patient is deceased, or after last scanning, whichever is applicable.

3000-E-30 <u>Daily radionucleide dosage logs</u>, showing the amount, nature, dates and purposes of radionucleides dispensed to patients in testing.

Located in Nuclear Medicine Department.

Disposition: Destroy when 1 year old.

3000-E-31 <u>Isotope Data Files on Patients</u> maintained by the Radiation Safety Branch, ORS: see item 1300-B-11.

3000-E-32 <u>Patient temperature, pulse, and respiration (TPR) sheets</u> posted to patients' folders. Located in Nursing Services.

Disposition: Destroy when posted.

3000-E-33 <u>Intake-Output records</u>, showing amounts ingested and excreted by patients. Posted to patients' folders.

Located in Nursing Services.

<u>Disposition</u>: Destroy when posted.

3000-E-34 Plan of care for each patient in surgery.

Located in Surgical Services Department.

<u>Disposition</u>: Destroy when 1 month old.

3000-E-35 Receiving Records, including identification and description of blood products for transfusion received from other collection facilities.

> Located in: CC, Transfusion Medicine Department.

Disposition: Retain on-site for 50 years or expiration of the patient or subject,

whichever is longer. Transfer to the Federal Records Center for 30

years. Destroy when 30 years old. (21CFR606)

Serological Test Records for Clinical Center patients: showing results of blood 3000-E-36 typings, antibody screening and compatibility testing.

(NOTE: These records are part of Privacy Act system of records 09-25-0011).

Located in CC, Transfusion Medicine Department.

a. Recordkeeping copy:

Disposition: Destroy the recordkeeping copy 5 years after patient is

discharged.

b. Electronic copies created on electronic mail and word processing systems:

Disposition: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

3000-E-37 Transfusion Service Records: Interpretations of adverse reactions to transfusion, identification of clinically significant antibodies, and special transfusion requirements for Clinical Center patients. NOTE: These records are part of Privacy Act system of records 09-25-0011).

<u>Located in CC</u>, Transfusion Medicine Department.

a. Recordkeeping copy:

Retain the recordkeeping copy on site for 50 years or upon Disposition:

notification of expiration of the patient or subject, whichever is

longer. Transfer to the FRC following on site retention for 50 years or notification of expiration of the patient or subject. Destroy after 30 years retention at the Federal Records Center.

b. Electronic copies created on electronic mail and word processing systems:

<u>Disposition</u>: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

3000-E-38 Patient Rehabilitation Files, pertaining to patients treated in the department, and containing physician referrals, progress notes, copies of X-ray interpretations, daily progress notes, copies of laboratory test results, and copies of outside physical therapy reports. Record copies of key documents are in the patients' folders in the Medical Records Department.

Located in CC, Rehabilitation Department.

<u>Disposition</u>: Destroy 10 years after last visit, or when patient is deceased, if the record is not involved in an ongoing study.

3000-E-39 <u>Social work patients' records</u>, containing copies of social work history sheets showing summaries of work done, patient responses, and related comments and papers. Record copies of the history sheets are in the patients' folders in the Medical Records Department.

Located in Social Work Department.

Disposition: Destroy 5 years after patient is discharged.

3000-E-40 Spiritual Ministry Patient Name Files, identifying Clinical Center patients.

Disposition: Destroy 6 months after patient is discharged or deceased.

3000-E-41 Patients' Travel and Transportation records.

Located in CC, Outpatient Department.

<u>Disposition</u>: Destroy when 3 years old.

Blood Donors

3000-E-50 <u>Donor History and Consent Records</u>: Multi-use forms each of which shows name of donor, medical history and physical data. Form includes a "tear-off" receipt portion documenting use of the blood in a nursing unit, and a detachable statement of donor's consent for blood to be drawn. (NOTE: These records are part of Privacy Act System of records 09-25-0011)

Located in CC, Transfusion Medicine Department.

a. History and physical data, and donor's consent portions.

<u>Disposition</u>: Destroy after microfilming and verification of film.

b. Microfilm copies.

Disposition: DISPOSAL NOT AUTHORIZED. Review with NIH

Records Management Officer for disposition when 15 years

old.

c. Receipt portions.

Disposition: Transfer to the Federal Records Center annually; destroy

when 5 years old.

3000-E-51 <u>Donor history sheets</u>, showing results of blood tests. Data are posted to computer. However, data for employee donors are removed from computer when employee leaves. On reemployment, antigen data are needed.

Located in CC, Transfusion Medicine Department.

Disposition: DISPOSAL NOT AUTHORIZED at this time.

Normal Volunteers

Records about individual clinical research volunteers who serve as controls in clinical studies.

EXCLUDED from this section are:

Records related to sponsoring agencies (see item 1100-J-5).

3000-E-61 <u>Inpatient normal volunteer files</u>, containing medical histories, appointment papers, admission sheets, and related correspondence and data.

<u>Disposition</u>: Destroy 3 years after volunteer period ends.

3000-E-62 <u>Copies of normal volunteer visit reports</u>, showing time spent by the volunteer, and payment made to the volunteer.

<u>Disposition</u>: Destroy when 2 years old.

iii. Nursing, Surgical and Other Patient Services

Operational records of Nursing, Surgical, Outpatient and Rehabilitation Departments of the Clinical Center.

EXCLUDED from this section are:

Records about individual patients (see subsection 3000-E-ii).

3000-E-71 <u>Administrative nursing reports and related papers</u>, submitted daily by each nursing unit, showing the number of patients, admissions, discharges, deaths, and other information about the patients.

Disposition: Destroy when 3 months old.

3000-E-72 <u>Daily nursing service reports</u>, showing employee absence and tardiness, and personnel reassignment and utilization.

Disposition: Destroy when 3 months old.

3000-E-73 <u>Patient Care Audit records</u>, relating to audits of the quality of patient care in the Nursing Department.

<u>Disposition</u>: Destroy when 5 years old.

3000-E-74 <u>Nursing unit reports</u>

Disposition: Destroy when 6 months old.

3000-E-75	See 3000-E-10
3000-E-76	Operating room log: Ledger records of operations performed, showing surgeon, assistants, and other vital data on each operation.
	<u>Disposition</u> : Destroy when 8 years old.
3000-E-77	Surgical scheduling requests
	<u>Disposition</u> : Destroy when 3 months old.
3000-E-78	Operating room memoranda. Posted to operating room log.
	<u>Disposition</u> : Destroy when posted.
3000-E-79	Daily operations listing
	<u>Disposition</u> : Destroy when 3 years old.
3000-E-80	Daily schedules of outpatients
	Located in Outpatient Department.
	<u>Disposition</u> : Destroy when 2 months old.
3000-E-81	General patient activities files, containing correspondence, memoranda, reports, purchase orders and related papers pertaining to activities developed for patients.
	<u>Disposition</u> : Destroy when 2 years old.
3000-E-82	Patients' library card files, showing patients who may charge library materials.
	<u>Disposition</u> : Destroy when patient is discharged.

iv. Volunteer Services

Records related to auxiliary services in the Clinical Center provided by volunteers from the general public, the Red Cross and other institutions.

3000-E-90 <u>Volunteer services case files</u>, containing applications, discharges, agreements and related correspondence regarding persons donating their services to the Clinical Center.

<u>Disposition</u>: Destroy 18 months after end of volunteer's service.

3000-E-91 <u>Administrative files concerning volunteer services</u>, containing correspondence, reports and related papers concerning daily operations.

Disposition: Destroy when 2 years old

F. Laboratory Operations, Materials and Resources

Records concerning laboratory performance, equipment and instrument maintenance and use, test media and preliminary processing of laboratory test results in clinical or research laboratories.

EXCLUDED from this section are:

- (1) Clinical and Research data records (see sections 3000-E and 3000-G through K);
- (2) Records concerning laboratory safety (see section 1300-B);
- (3) Records on production and supply of laboratory animals (see section 3000-C);
- (4) Records created in the development of laboratory instruments and data processing systems (see section 3000-D and 2800-A).
- 3000-F-1 Quality Control Records, consisting of charts, graphs, and other records showing the quality of laboratory performance, and reflecting the adequacy of laboratory procedures and/or equipment.

<u>Located in CC</u>, Clinical Pathology Department.

<u>Disposition</u>: Destroy when 2 years old.

3000-F-2 <u>Instrument Maintenance Records</u>, documenting repairs or other adjustments made to instruments used in the department.

Located in CC, Clinical Pathology Department.

<u>Disposition</u>: Destroy when instrument is no longer used.

3000-F-3 <u>Log Books, Recorder Charts, and Other Working Papers</u> used to prepare reports or analyses.

Located in CC, Clinical Pathology Department.

<u>Disposition</u>: Destroy when 30 years old.

3000-F-4 <u>Laboratory Testing Records</u>. Includes documentation of pre- and post-analytical phases of testing process and all laboratory data generated in the analytical phase, including quality control, observed values and Interpretations associated with patient testing. Used for reference and research.

Located in: CC, Transfusion Medicine Department.

<u>Disposition</u>: Destroy when 2 years old, or when no longer useful for research. (42CFR493).

3000-F-5 <u>Process Control Records.</u> Laboratory and manufacturing control records associated with patient testing, donor testing, or blood product manufacturing. Includes documentation related to validation, maintenance and quality assurance of equipment, supplies, reagents and processes. Used for reference and research.

Located in: CC, Transfusion Medicine Department.

Disposition: Destroy after 5 years, or 6 months after any blood product

associated with these records has expired, or when the data is no

longer useful for research, whichever is the latest date.

(21CFR606).

3000-F-6 to 3000-F-9: Reserved

3000-F-10 <u>Media Preparation Case Files and Indexes</u> related to requisitions for laboratory media and cells, including description of the method of preparation and the ingredients used.

Located in CC, Clinical Pathology Department.

<u>Disposition</u>: Destroy after 10 years.

3000-F-11 Media Formulas

Located in CC, Clinical Pathology Department.

<u>Disposition</u>: Destroy after 10 years.

G. <u>Biomedical Research Projects: General</u>

Records related to planning, development and oversight of specific projects and programs of biomedical research performed by NIH investigators, contractors and/or collaborative research and development agreements (CRADAs); includes experimental, observational and control data generated in such research and the products of research such as articles, reports and data sets. Use this section only for records not specifically identified in items 3000-H through 3000-K.

EXCLUDED from this section are:

- (1) Broad scope and long-term research planning and review files at IC and higher levels (see section 1100-C);
- (2) Research records containing data relevant to patent and invention rights (see item 1100-L-1).
- (3) Records of clinical trials, drug testing and development and other clinical research identified in section 3000-H.
- (4) Records of epidemiological and biometric research identified in section 3000-I.
- (5) Records of laboratory experiments identified in section 3000-J.
- (6) Critically analyzed data and reference data identified in section 3000-K.
- (7) Records of the Veterinary Resources Branch (see section 3000-C).

3000-G-1 <u>Planning and Development Records for Research Projects</u>: Included are objectives, plans and protocols, clearances and authorizations schedules, directives and other records accumulated by the ICs in establishing research projects. (Excluding research protocols specified in item 3000-G-2).

<u>Disposition</u>: Transfer to Federal Records Center 2 years after the project is completed or discontinued. Destroy after 17 years after termination. Earlier disposal is authorized if the project leader determines they are no longer needed for scientific reference.

3000-G-2 Research Protocols

a. Concerning standards and procedures to be followed in use of animals in research.

<u>Disposition</u>: Destroy when protocol is no longer in force.

b. <u>Clinical Center Protocol files</u>, documenting proposals made by the Institutes and approved by the Director of the Clinical Center for use of human subjects in research, development, and related activities. Each file normally contains the official copy of the protocol, describing the nature of the proposed research, the methodology involved, projected aims and justifications, notations and records of approval actions, names of principal investigators, project reviews, and related correspondence and memoranda.

Located in CC Medical Record Department.

Disposition: PERMANENT. Review closed files at 5-year intervals and transfer

those which are no longer needed for reference to the Federal Records Center. Offer to the National Archives 5 years after

transfer to the Records Center.

c. Copies of research protocols, showing the research purposes for which normal volunteers are to be used.

Located in CC, Office of Normal Volunteers.

Disposition: Destroy 1 year after end of research project.

Records of Basic Experimental and Statistical Data collected or developed for each research project. Any or all of the following are included: logs, notebooks, cards, forms or other media on which observations and data are recorded; records on patients or normal volunteers of interviews, questionnaires, examinations, or laboratory tests, including machine readings and data from slides, specimens or cultures; copies of abstracts of non-clinical records on individuals such as birth and death certificates; records created in processing and analyzing data related to or resulting from the project, including indexes, code cards and sheets, charts, graphs, punch cards, computer output in paper or microfilm form, tabulations, diagrams or drawings, etc.; and intermediate compilations or analyses and progress reports with feeder reports and background material.

When records in this series have been microfilmed in accordance with the standards set forth in 41 C.F.R. 101-11.506, the microform may be retained in accordance with the instructions in 'b' below, and the originals from which the microfilm was made may be destroyed in accordance with 'a'.

For records which may be needed in establishing patent or invention rights, see section 1100-L.

Note: The official medical records of the Clinical Center patients are not included in the series. (See item 3000-E-22.)

a. Original full-sized copies of records which have been microfilmed, when the microfilming has been done in accordance with the standards set forth in 36 CFR 1230.

<u>Disposition</u>: Destroy originals when microfilm copies have been examined and shown to be acceptable.

b. Original records which have not been microfilmed, and microfilm or microfiche masters produced in accordance with the standards set forth in 41 C.F.R. 101-11.506.

Disposition:

Destroy when the project leader or principal investigator determines that the records are no longer useful for research. Inactive records which need to be kept for more than 3 years may be transferred to a Federal Records Center for storage, provided that the project leader specifies in advance of transfer the month and year when the records are to be destroyed.

NOTE: When sending this record series to the Federal Records Center (FRC) for long-term storage, the research/PI must indicate the disposal date on the SF-135,"Records Transmittal and Receipt," under item 6i, Disposal Date. Also, the following statement must be added to the bottom of item 6f, Series Description, i.e.:

"These records are eligible for	
destruction on mo/yr."	

Signature Date

3000-G-4 End Products of each research project which report findings and conclusions, document advancements in treatment of disease or development of new medical devices or are unique clinical records which have potential value in continuing research. Included are summary or final project reports, article reprints, monographs, graphic compilations and analyses.

<u>Disposition</u>: <u>PERMANENT</u>. Transfer one complete set to the Federal Records Center. Offer to National Archives when 20 years old.

H. Clinical Research

Records generated or collected in research programs which aim specifically and directly at developing, identifying, improving, testing or evaluating methods, procedures, tests, instruments or drugs used in any aspect of medical practice. This section includes records of preclinical screens, clinical trials and drug testing and development.

EXCLUDED from this section are:

- (1) Records kept for clinical care rather than research (see section 3000-E).
- (2) Records of biomedical research not directly related to specific clinical applications (see section 3000-G, I or J).
- (3) Records of the Veterinary Resources Branch (see section 3000-C).
- i. <u>Drug Testing and Development Records of the Clinical Center Pharmaceutical Development Service.</u>
- 3000-H-1 <u>Statements of Responsibility and Certifications of Drug Release</u>: By signing this form, a physician assumes responsibility for the use of drugs not yet fully tested.

Located in CC, Pharmacy Department.

Disposition: Destroy when 5 years old.

3000-H-2 <u>Pyrogen Test Records</u>, showing the results of testing drugs for certain harmful characteristics.

Located in CC, Pharmacy Department.

<u>Disposition</u>: Destroy 2 years after new drug application is approved or

disapproved; if no new drug application is filed, destroy 2 years

after study is completed.

3000-H-3 Requests for Testing of Developmental Drugs

Located in CC, Pharmacy Department.

<u>Disposition</u>: Destroy 2 years after new drug application is approved or

disapproved; if no new drug application is filed, destroy 2 years

after study is completed.

3000-H-4 <u>Investigational Drug Service Requests</u>: Doctors' notifications to the department of intent to use a drug not yet approved for general use.

Located in CC, Pharmacy Department.

<u>Disposition</u>: Destroy 2 years after the new drug application is approved or

disapproved; if no new drug application is filed, destroy 2 years

after study is completed.

3000-H-5 <u>Tally records of technical work done</u>, used to prepare workload reports.

<u>Disposition</u>: Destroy when 1 month old.

ii. Registries.

These registries comprise the compilation of data items and supporting documents specific to the stated purpose of the registry. Examples of such registries would include collections of information on: potential bone marrow donors, end-stage renal disease, Burkitt's Lymphoma, etc.

EXCLUDED from this section are:

- (1) Records about Project Officers' Files (see 6000-B-1).
- (2) Procurement records (see 2600-A-4).

3000-H-10 Registries.

a. A central system used to collect and maintain the information for the

purpose of which the registry was developed.

<u>Disposition</u>: Destroy when no longer needed for administrative use and/or scientific research.

b. <u>Input/Source Files</u> used for updating the registry. These records may be in electronic or hardcopy form.

<u>Disposition</u>: Destroy when information has been converted into the registry and verified. (GRS 20, items a. or b.)

c. <u>Other Components Records</u>: Records maintained by other components that augment the registry records.

<u>Disposition</u>: Destroy when no longer needed for administrative use and/or scientific research.

d. <u>Procurement Files</u>.

<u>Disposition</u>: Destroy with related contract case file (2600-A-4).

e. <u>Reports</u> that are prepared and submitted as required by the registry. For example: technical reports; quarterly, semi-annual, or annual reports; project summaries; final report. [Refer to 6000-B-1-b for records which constitute a contract deliverable].

<u>Disposition</u>: Transfer record copy of reports to the Federal Records Center in five year blocks. Destroy when 20 years old.

I. <u>Epidemiology and Biometry</u>

Reserved.

J. Laboratory Experiments

Reserved.

K. Critical and Standard Reference Data

Page 23		
Appendix	1	

Reserved.

Last update 9/21/99